NEWMOA Technology Review Committee

Advisory Opinion

Innovative Technology: Immunoassay Field Analysis

Date of Opinion: May 24, 1999

Project Background:

Regulatory and institutional barriers to the adoption of innovative hazardous waste site assessment technologies can result in increased expenditures to evaluate and remediate contaminated sites. Because innovative technology has the potential to clean up and protect the environment and the public's health in a more cost-effective and efficient manner, finding ways to encourage their increased use is crucial.

Recognizing the need to overcome barriers to the acceptance of technology innovation, the six New England States, EPA Region I - New England, the Northeast Waste Management Officials' Association (NEWMOA) and the New England Governors' Conference signed a Memorandum of Agreement (MOA) in March 1998 to promote interstate regulatory cooperation for waste site assessment and cleanup technologies. Subsequently, NEWMOA has worked closely with EPA Region I and the Northeast Hazardous Substances Research Center (NHSRC) to increase the understanding of the factors that discourage the use of innovative technologies. NEWMOA held meetings and conference calls with NEWMOA's Waste Site Cleanup Workgroup and co-sponsored, with NHSRC a Stakeholders Workshop held in May 1998 called "Increasing the Use of Innovative Technologies on Small Hazardous Waste and Petroleum Sites." The focus of this Workshop was on building consensus among the stakeholders regarding practicable measures to reduce or eliminate obstacles to the use of innovative site assessment technologies.

At the May 1998 Stakeholder Workshop, participants identified the lack of an interstate forum in the Northeast to actively review technologies and communicate both public and private sector use of innovative technologies as a major impediment to the overall marketability of the newer field analytical, characterization and monitoring technologies. To address this need, NEWMOA has established a Technology Review Committee (TRC), made up of one or more staff members from each of the Northeast states[(1)] to coordinate state review, issue advisory opinions and disseminate information on the use of innovative technologies.

The purpose of this Advisory Opinion is to raise awareness of immunoassay technology and its application in the Northeast. This Advisory Opinion is intended to communicate TRC interest in the use of immunoassay technology to potential users of hazardous waste site characterization technology, such as consultants, as well as to project managers within the various state site cleanup programs. The Advisory Opinion is also intended to educate consultants and the state regulators who oversee projects about the factors that can affect the proper use of immunoassay technology.

All seven of the Northeast states participated in the development of this Advisory Opinion consensus statement. In addition, the technical information was reviewed by U.S. EPA Region I and a vendor of immunoassay technology. However, it should be noted that this Advisory Opinion is not intended to be an "approval" of this technology. The appropriateness of the use of immunoassay technology will need to be determined on a site-by-site basis. Potential users should contact officials in the state in which the project is located to determine if there are any state-specific requirements that could apply.

Overview of Technology:

The primary advantage of immunoassay analysis over laboratory analysis is that analytical results can be generated in real-time allowing decision-making in the field regarding the need for additional sampling or further remediation (provided that proper data validation procedures are followed). Immunoassay test kits have been designed to be relatively easy-to-use (compared to laboratory analysis) and can provide results for numerous samples in a relatively short timeframe. For example, some kits can provide results for up to 20 samples in one hour.

Immunoassay test kits have been developed to be specific to individual compounds such as individual pesticides or to be

sensitive to compound groups such as PAHs, PCBs or petroleum hydrocarbons. Many immunoassay test kits have undergone significant validation and are SW-846 Methods. There are SW-846 method immunoassay kits for the following analytes:

Analyte	**SW-846 Method**
Pentachloro Phenol (PCP)	4010A
2,4 Dichlorophenoxy Acetic Acid in soil	4015
Polychlorinated Biphenyls (PCBs) in soil	4020
Total Petroleum Hydrocarbons (TPH) in soil	4030
Polynuclear Aromatic Hydrocarbons (PAH) in soil	4035
Carcinogenic PAH in soil	4035
Toxaphene in soil	4040
Chlordane in soil	4041
DDT in soil	4042
trinitrotoluene (TNT) in water and soil	4050
Hexahydro-1,3,5-Trinitro-1,3,5-Triazinc (RDX) in water and soil	4051
Triazene in water	4670

Note that for a particular analyte not all kits from all manufacturers are SW-846 methods. In addition, there are kits for additional analytes that are not SW-846 methods, but might provide useful information at a particular site. Finally, immunoassay technology vendors are engaged in the development of kits for additional analytes that might become SW-846 methods. Potential users should check with vendors and/or the U.S. EPA to determine the current listing of analytes for which immunoassay test kits have been developed and their SW-846 status.

Some test kits are designed to yield qualitative results (e.g. the contaminant is or is not present), while some provide semi-quantitative results (e.g. the contaminant is above, below or between two specified levels) and still others can produce quantitative results with low detection limits. If properly utilized, some immunoassay tests allow for relatively specific analysis of organics to sub-parts per million (ppm) levels in soil and sub-parts per billion (ppb) levels in water.

When combined with simple field sample preparation techniques, immunoassay technology can be used to analyze many different types of environmental matrices, including water, soil, surfaces (wipes), sediments, sludge, compost and concrete. Water samples usually require minimal sample preparation (e.g. filtering) and are usually analyzed directly. Soil and wipe samples typically require the use of relatively simple and fast field extraction procedures, which might be combined with extract dilution prior to immunoassay analysis.

Several different types of PCB immunoassay test kits have been evaluated in the EPA's Environmental Technology Verification (ETV) Program. The Technology Verification Statements for the evaluated PCB immunoassay kits as well as more information about the ETV Program itself can be obtained at http://www.epa.gov/etv or by calling U.S. EPA Region I at (617) 575-CEIT.

Immunoassay technology has been used for site characterization or cleanup monitoring at over 40 Superfund sites, including several Department of Defense (DOD) and Department of Energy (DOE) facilities.[2] U.S. EPA Region I has used immunoassay technology at several sites in New England and published *Immunoassay Guidelines for Planning Environmental Projects* in

October 1996. The guidelines can be obtained at http://www.epa.gov/region01/measure/ia/iaguide.html or by calling (617) 575-CEIT. In addition, several Northeast states have successfully used immunoassay technology during site characterization and/or remediation, including Maine, Massachusetts, New York, Rhode Island, and Vermont. The New York State Department of Environmental Conservation Division of Environmental Remediation has issued *Quality Assurance Guidelines for Using Immunoassay Field Screening*, which can be obtained by calling (518) 457-9280.

Recommendations:

The Technology Review Committee has determined that, if used properly, immunoassay technology can provide useful data that should improve site characterization and/or cleanup verification. Potential users of immunoassay technology are strongly urged to consult U.S. EPA Region I's *Immunoassay Guidelines for Planning Environmental Projects* (October 1996) (http://www.epa.gov/region01/measure/ia/iaguide.html) and kit vendors prior to planning the field effort. The TRC recommends the following items to improve or insure product performance; however, users should recognize that a particular test kit might have additional requirements:

- Potential users of immunoassay guidelines should consult Section 7, Practical Planning for Projects Using Immunoassay of U.S. EPA Region I's *Immunoassay Guidelines for Planning Environmental Projects* (October 1996) and follow the project planning methodology outlined in Figures 6 and 7 of that document (and also attached to this Advisory Opinion). For example, in order to use immunoassay test methods effectively, the type of contamination and its relative concentration must be predetermined. In addition, the intended use of the data and data quality objectives (DQOs) also must be determined prior to the sampling and analysis event.
- Personnel who use immunoassay kits must be qualified and should receive formal training including an explanation of immunoassay theory, how the specific method works, quality assurance/quality control requirements and methods, and how to interpret the results. The immunoassay test kit vendors typically offer this type of training upon request. The performance of users should be evaluated by correlation of the analyst's results from the quality assurance/quality control (QA/QC) analyzes (described in item number 3 below) to the acceptance criteria developed in the DQOs.
- To obtain reliable results, users should carefully follow the manufacturers instructions - the sequence and timing of steps is critical for the technology to work properly. In addition, the following QA/QC measures should be undertaken, at a minimum:
  - Calibration standards with each run (typically supplied in the kit)
  - Blanks (methanol, lab-prepared matrix blank, and if possible, a field blank) at the beginning and end of each day
  - Spikes (methanol and lab-prepared matrix spike) at the beginning and end of each day
  - Performance evaluation sample once a day
  - Duplicates at one every 10 samples
  - Laboratory confirmation on at least 10 percent of samples by EPA Method 8000 Series, or another appropriate EPA-approved method.

- Users are expected to record the results of the QA/QC samples and evaluate them daily to ensure that the analyses and QA/QC checks are performing according to the criteria established in the vendor literature and the project DQOs.
  - Immunoassay kits must not be used in direct sunlight. When the kits are used, the temperature should be between 13-27ºC (55-80ºF).
  - Immunoassay kits have defined shelf-lives and storage condition requirements. Kits should be ordered from the manufacturer as they are needed.
  - Soil samples should be handled following standard procedures to promote consistency and comparability

of results and to minimize volatilization.

- The presence of certain compounds, particularly at high concentrations can interfere with the performance of certain immunoassay tests. The user should be aware of possible cross-reactions and matrix effects and test kit vendors can typically provide the necessary information during the planning stage.
- When used properly, some immunoassay tests can give good estimates of the range in which the true concentration lies. Personnel should not rely on the specific result generated by a quantitative immunoassay test kit. If a soil sample is silt/clay, is heterogeneous, has a high total organic carbon content, has a high moisture content and/or contains a high percent of volatile compounds, the sources of variation (error) become much greater (with both an immunoassay test and laboratory analysis). For water samples, factors such as turbidity, pH, salinity and color can interfere with the immunoassay test itself and/or the users ability to interpret the results.
- To address the concerns raised above, particularly in Numbers 7 and 8, it is recommended (and could be required in states that pre-approve work plans) that a potential user conduct the chosen immunosassay test(s) on two or three samples from the site before the full-scale effort is undertaken to determine whether immunoassay is appropriate for use at that particular site.
- Immunoassay tests are designed to have a bias towards false positives. Users should not be surprised if immunoassay results exceed laboratory results.

The NEWMOA Technology Review Committee has issued this Advisory Opinion on this 24th day of May 1999.

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1. In this document, the Northeast states are: Connecticut, Maine, Massachusetts, New Hampshire, New York, Rhode Island and Vermont.

2. U.S. EPA, *Field Analytical and Site Characterization Technologies, Summary of Applications*, EPA-542-R-97-011, November 1997.